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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,625	02/01/2001	Jana Sawynok	DALHO1290-1	7582

7590

07/20/2004

STEPHEN E. REITER
FOLEY & LARDNER
P. O. BOX 80278
SAN DIEGO, CA 92138

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,625

Applicant(s)

SAWYNOK ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-44, 49-53 and 73-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-44, 49-53 and 73-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 37-44, 49-53 and 73-79 are pending.

The following rejection of 9-3-2003 has been maintained:

Claim Rejections - 35 USC § 112

1. Claims 37-41, 73 and 79-83 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claims are amended to exclude the second and third generation antidepressants that are not 5-HT₂ receptor antagonists, which is not supported by the specification. Instant specification does not describe or exemplify compositions containing second and third generation antidepressants with the claimed negative limitation and accordingly is anew matter. If applicants wish to claim all the second and third generation antidepressants other than 5-HT₂ receptor antagonists, it is suggested that applicants list the desired compounds in a markush format.

Response to Arguments

Applicant's arguments filed 3-10-2004 have been fully considered but they are not persuasive.

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Applicants state that the limitation “second and third generation antidepressants are not 5-HT2 receptor antagonists” is fully supported by the instant invention and does not constitute new matter. Applicants refer to page 5 (lines 10-13) and examples 3 and 4 of the instant specification for supporting statements and examples. Applicants argue that in light of the above, instant exclusion of antidepressants that are 5-HT2 receptor antagonists is fully supported. However, a careful review of the specification indicates that the support on page 5 is only a conclusion or results derived from prior art references and not the embodiments of the invention described by applicants. Besides, if applicants’ statement (example 4) that “it is not shown that 5-HT2 antagonism accounts for the analgesia demonstrated by amitriptylline and other cyclic, second and third generation antidepressants observed” were true, then the activity shown by all antidepressants should be independent of 5-HT2. In such an instance, how can one exclude the activity that is not due to 5-HT2? Therefore, for reasons mentioned, the rejection has been maintained.

Further, the instant amendment to claims 42, 44 and 49-51 have rendered the claims dependent upon claim 37. Accordingly, the above claims are also rejected as lacking support for the above limitation and thus constitute new matter rejection.

Should applicants amend the above claims by deleting the new matter, the following rejections of record will be applied, for the reasons explained in the previous actions:

1. Rejection of claims 37-43, 73, 74, 76, 79 and 81 under 35 USC 102(b) as being anticipated by Amer (US 5,266,571) and

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2. Rejection of claims 75, 77, 78, 80, 82 and 83 under 35 USC 103(a) as being unpatentable over Amer in view of Knapp et al

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

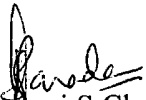
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

July 13, 2004



Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600